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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,136	02/04/2004	Yougandh Chitre	A04P1013	5083
36802	7590	10/06/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,136

Applicant(s)

CHITRE ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/4/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5, 6, 8, 9, 11-13, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Pravorerov et al. (Pat. No. 4,273,137).

Regarding claim 1, Pravorerov et al. disclose a biocompatible, biostable, corrosion-resistant wire strand comprising a core (see Fig. 2) comprising a plurality of electrically conductive, low electrical resistance filaments 7 embedded in an electrically conductive matrix (stainless steel alloy tubes 6), and a low electrical resistance, substantially chemically inactive cladding (stainless steel alloy sheath 8). The term “low electrical resistance” was considered, but deemed to be a relative term and encompassing of materials that conduct electricity when compared to insulator materials.

Regarding claim 6, note the use of titanium in the alloy of example II (col. 3, lines 9-15).

Regarding claim 11, note the use of palladium in example V of col. 3.

Regarding claim 12, the fiber with filaments is braided as discussed in col. 2, lines 54-60.

Regarding claim 13, comments made above in the rejection of similarly worded claim 1 apply here as well, with the terminal contact represented by element 5. Concerning the recitation of at least one electrode comprising a wire strand, the examiner considers element 4 with braid 2 connected to it in combination to be an electrode with a biocompatible, biostable, corrosion-resistant wire strand attached. The claim as written does not require the electrode to consist of only the exposed wire.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pravorerov et al..

While Pravorerov et al. simply refer to the use of the lead in a cardiac electrostimulator, it is not explicitly stated that the electrode is used for pacing or for cardioverting and/or defibrillating. Those of ordinary skill in the cardiac stimulation arts, however, would have considered the disclosure of Pravorerov et al. to suggest its use at least in endocardial pacing as the configuration is standard in the pacing arts, and pacers are well-known electrostimulators. Whether an electrode is used to pace or cardiovert/defibrillate depends upon the intended use for the electrode and the capabilities of the therapy system the electrode is connected to. A traditional pacing electrode may be used to revert arrhythmias such as tachycardia or fibrillation and therefore can be considered a cardioverting or defibrillating electrode. The applicants recite no limitations involving means for generating high-energy pulses or limitations concerning electrode surface area and therefore do not preclude such interpretations. The examiner would further argue that those of ordinary skill in the art would have recognized the ability of the braided strand of Pravorerov et al. to carry energies typically associated with cardioversion or defibrillation and therefore would have seen the obviousness of using the same braided strand in what would be considered a typical defibrillation lead.

Claim Rejections - 35 USC § 103

5. Claims 3, 4, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pravorerov et al. (Pat. No. 4,273,137) in view of Verness.

Regarding claims 3 and 4, while Pravorerov et al. do not explicitly refer to the wire strand's manner of construction (DFT or DBS), such a limitation is considered to represent a product-by-process claim. The structure resulting from the process appears to be identical to that of the applicants' invention. In any event, Verness teaches that DFT and DBS are well known and standard fabrication processes in the art for creating wires (col. 11, lines 1-13). Those of ordinary skill in the art would have considered their incorporation into the fabrication process of the Pravorerov et al. invention a matter of obvious manufacturing expediency lacking any specific direction by Pravorerov et al. against their use.

Regarding claim 7, while the plurality of filaments comprise silver, Pravorerov et al. do not discuss the use of MP35N in the construction of the matrix, but rather stainless steel (and cobalt alloy similar to MP35N). As is old and well-known in the industry, MP35N can be used in place of stainless steel as taught in the text abridging cols. 10 and 11 of Verness. To use MP35N in place of stainless steel for its widely recognized properties of durability, biocompatibility and relative inexpensive cost, would have been seen by those of ordinary skill to be an obvious materials choice in view of the teachings of Verness.

Regarding claim 10, while Pravorerov et al. does not explicitly discuss the percentage weight of filaments to core, this particular range of filament to core weight would have been suggested to one of ordinary skill in the art given that both inventions employ silver and, as argued above, MP35N, in wire strands used in implantable cardiac leads which require similar flexibilities, mechanical strengths and electrical properties. Those of ordinary skill in the art desiring a reasonably flexible, mechanically strong, and highly conductive lead would have considered the exact weight ratio to be a matter of obvious design with tradeoffs between cost and conductivity dictating the relative weight of precious metal used.

Regarding claim 18, comments made above in the rejection of similarly worded limitations apply here as well.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS
September 29, 2006


KENNEDY SCHAETZLE
PRIMARY EXAMINER